Appl. No.: 09/724,691
Amdt. Dated: 11/17/2003
Off. Act. Dated: 07/17/2003

REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and discussion presented herein.

1. Election of Species Requirement.

The Office Action noted withdrawal of Claims 6-7 and Claims 12-15 as being drawn to non-elected Species per a prior Office Action, and noted Applicants' timely traversal related to inclusion of these claims as similar subject matter, which argument was not agreed to in the Office Action. Applicants acknowledge the determination in the Office Action that Claim 1 is generic to the withdrawn dependent claims, and therefore requests rejoinder in the event Claim 1 is considered allowable.

2. Rejection of Claims 1, 8-11, 16-20 under 35 U.S.C. §102(b) based upon Cox (U.S. 5,257,974).

As a basis for this ground for rejection, the Office Action stated the following:

> Cox teaches a catheter with an elongated shaft; a tubular member 160 on a distal section of the shat (shaft) having an interior passageway which is radially expandable within a blood vessel to separate blood glow (flow) though (through) the blood vessel into an outer blood flow stream exterior to the tubular member and an inner blood flow stream within the interior passageway of the tubular member, a radially expandable member 194 having an expanded configuration with an outer diameter larger than an outer diameter of the tubular member.

Applicant's have amended independent claims 1 and 18 to clarify that the assemblies of the present invention are adapted to provide inter-cooperative operation of elements that provide bilateral renal delivery of therapeutic agents from a location within an abdominal aorta and according to modified blood flow patterns within the abdominal aorta. Such an assembly is not anticipated or suggested in the cited Cox reference.

Cox discloses use of an adaptor with balloons of intravascular balloon catheters. The balloon catheter is positioned within a blood vessel; the adaptor is capable of longitudinal movement through the blood vessel, between the balloon catheter and a

wall of the blood vessel, independent of the balloon catheter. The adaptor is maneuvered adjacent to the balloon by manipulating the positioning member until a proximal end and a distal end of the adaptor is generally aligned with a proximal and distal end of the balloon, respectively. Inflation of the balloon secures the follow member against the balloon in such a manner that the characteristics of the hollow member are imparted to the balloon. (Abstract)

More specifically, the suspect disclosure referenced in the Office Action refers to element 160 which is disclosed as a perfusion adaptor 160 that generally includes a coil member 162 and positioning member 164. Coil member 162 is comprised of a series of individual coils 166, with each coil 166 separated from an adjacent coil by space 168. Collectively, inner surfaces 172 of coils 166 define a generally cylindrical flow passage 174. However, this is only the case when perfusion adaptor 160 accommodates intravascular conditions encountered in the course of intravascular balloon catheter procedures. As shown in FIG. 10A, coil member 162 is positioned adjacent balloon 194, and so positioned a flow path 174 is maintained. Flow path 174 permits flow of blood past balloon 194 when it is inflated. Spacings 168 of coil member 162 allow blood flowing through flow passage 174 to flow generally transverse to flow path 174 and into side branch 190. (col. 9, line 45 to col. 10, line 57)

Claim 1 (Currently Amended)

In contrast, the currently amended form of claim 1 clarifies that the originally claimed catheter for controlling flow to branch vessels from a main vessel is more specifically a "*catheter for controlling flow of fluids to a plurality of renal arteries via their respective renal ostia at unique relative locations along an abdominal aorta in a patient.*" The Cox disclosure does not describe or suggest such a catheter.

In one regard, amended Claim 1 requires a tubular member that must be "*radially expandable within the location along the abdominal aorta to a configuration that is adapted to separate blood flow through the abdominal aorta at the location into an outer blood flow stream exterior to the tubular member and an inner blood flow*

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stream within the interior passageway of the tubular member." The perfusion adaptor 160 in the Cox disclosure does not "separate" blood flow between such paths – rather it specifically provides spacings allowing for transverse communication between interior and exterior of the inner passageway.

In another regard, amended Claim 1 requires "*a radially expandable member located along the tubular member, and having an expanded configuration with an outer diameter larger than an outer diameter of the tubular member and which is configured to direct at least part of the blood flow in the outer blood flow stream into the renal ostium.*" Balloon 194 of the Cox disclosure is not such a radially expandable member as is required by Claim 1, as it is not located along the tubular member as part of one catheter, but rather is separate and distinct device. Moreover, there is no description or suggestion that such balloon 194 is adapted to direct at least part of the blood flowing in the outer blood flow stream (e.g. outside of perfusion adaptor 160) and into a side branch vessel, much less into a renal ostium.

Still further, Applicants have further amended Claim 1 to also now require a "*fluid agent delivery system*" that is adapted to "*couple to a source of fluid agent located externally of the patient*" and that is also characterized as "*cooperating with the tubular member and radially expandable member so as to deliver a volume of the fluid agent from the source and into the outer blood flow stream.*" No such fluid agent delivery system is described or suggested in the Cox reference.

Accordingly, based on the foregoing amendments to independent Claims 1 subject to this ground for rejection, as well as with respect to the claims that variously depend therefrom, Applicants respectfully reconsideration and withdrawal of this ground for rejection, and that the subject claims be allowed.

Moreover, Applicants note that the amendments to Claim 1 have been made herein in order to expedite examination of the Application toward a hopeful allowance in the next official action on the merits, and are made without prejudice, admission, waiver, or estoppel with respect to the patentability of the original form of th claims,

which Applicants believe are patentably distinct from the cited reference(s) in their original form. Applicants reserve the right to pursue the original form of these claims in the future, such as for example through continuation practice.

Claim 18 (Currently Amended)

With specific reference to Claim 18 as also currently amended, this method claim now requires a method for "*controlling blood flow to a plurality of renal arteries via their respective renal ostia at unique relative locations along an abdominal aorta in a patient.*" There is no description or suggestion within the Cox reference for such a method.

In one particular regard, the method of amended Claim 18 requires providing a catheter that has both (i) a radially expandable tubular member and also (ii) a radially expandable member on the expandable tubular member. As noted above with respect to distinguishing features of Claim 1, no such catheter is disclosed in Cox, which provides a perfusion adaptor for use in a "two-catheter system" with a separate balloon catheter.

In further regards, the method of amended Claim 18 also requires the following unique steps:

> "*advancing the distal end portion (of the catheter) to the location within the patient's abdominal aorta, so that an upstream end of the tubular member is upstream of the renal ostia and the radially expandable member is downstream of the renal ostia;*"
>
> "*expanding the tubular member to separate blood flow through the abdominal aorta into an outer blood flow stream exterior to the tubular member and an inner blood flow stream within the interior passageway of the tubular member;*" and
>
> "*expanding the radially expandable member to the expanded configuration to thereby decrease the blood flow in the outer blood flow stream downstream of the renal ostia.*"

None of these steps are described or suggested in the Cox disclosure. More

specifically, Cox does not describe or suggest: methods within an abdominal aorta for controlling flow to renal arteries via their ostia; placing an outer expandable member "downstream" of the renal ostia while an expandable tubular member spans within the abdominal aorta across the renal ostia; or decreasing blood flow in an outer blood flow stream around the tubular member downstream of the renal ostia.

Accordingly, based on the foregoing amendments to independent Claim 18 subject to this ground for rejection, as well as with respect to the claims that variously depend therefrom, Applicants respectfully reconsideration and withdrawal of this ground for rejection, and that the subject claims be allowed.

Moreover, Applicants note that the amendments to Claim 18 have been made herein in order to expedite examination of the Application toward a hopeful allowance in the next official action on the merits, and are made without prejudice, admission, waiver, or estoppel with respect to the patentability of the original form of the claims, which Applicants believe are patentably distinct from the cited reference(s) in their original form. Applicants reserve the right to pursue the original form of these claims in the future, such as for example through continuation practice.

3. Rejection of Claims 1, 8-11, 18-22 under 35 U.S.C. §102(b) based upon Johnson (U.S. 6,039,721).

As a basis for this ground for rejection, the Office Action stated the following:

> Johnson teaches a catheter with an elongated shaft; a tubular member 160 on a distal section of the shat (shaft) having an interior passageway which is radially expandable within a blood vessel to separate blood glow (flow) though (through) the blood vessel into an outer blood flow stream exterior to the tubular member and an inner blood flow stream within the interior passageway of the tubular member, a radially expandable member 194 having an expanded configuration with an outer diameter larger than an outer diameter of the tubular member; and a lumen 50 therein in fluid communication with the agent delivery port in a distal section of the shaft and wherein the radially expandable member is downstream of the agent port.

Applicant's have amended independent claims 1, 18 and 21-22 to clarify that the

assemblies of the present invention are adapted to provide inter-cooperative operation of elements that provide bilateral renal delivery of therapeutic agents from a location within an abdominal aorta and according to modified blood flow patterns within the abdominal aorta. Such is not anticipated or suggested in the cited Johnson et al. reference.

The support provided for this ground for rejection is identically the same as the prior statements with respect to Cox above, with the addition of "a lumen 50 therein in fluid communication with the agent delivery port in a distal section of the shaft and wherein the radially expandable member is downstream of the agent port." However, there is no tubular member 160, or radially expandable member 194 disclosed in Johnson et al., nor are those reference numbers found in the Johnson et al. disclosure. Nor are those structures found or suggested in Johnson as is required by the rejected claims.

Johnson discloses a balloon catheter having concentric, elongate lumen and guide tubes defining a lumen therebetween. An annular balloon has its proximal end secured to the lumen tube and its distal end secured to the guide tube. Relative axial movement of the tubes adjusts the balloon between retracted and extended positions. Processes for using the balloon catheter are disclosed to include performing angioplastic procedures on a plurality of stenosis of differing longitudinal extents during a single catheterization procedure, implanting self-expanding stents in blood vessels treating occluded blood vessels and apply medications to diseased blood vessels.

With particular respect to the provision for "lumen 50" as referenced in the Office Action, no such element is found according to Applicants' review of Johnson et al. Johnson et al. describes a medication carried by a hydrogel or other "*carrier 50*" applied to that section of the external surface of the balloon 26' which is adjacent to and surrounds lumen tube 15 when the balloon 26' is in its collapsed and foreshortened position (col. 8, lines 18-31). Lumen tube 15 is disclosed as an elongate cylindrically contoured tube concentrically disposed about the guid tube 14. To the extent

understood by the disclosure, a catheter control structure 16 has "an elongate through guide tube receiving passage 17", and is fixed to the proximal end of lumen tube 15. Tubes 14 and 15 are adjustable relative to each other longitudinally. This has nothing to do with drug delivery via a lumen into an exterior blood flow stream around an expandable tubular member, much less through a port upstream from another radially expandable member on the tubular member and that is located downstream of a renal ostium.

The multi-lateral aortic-to-renal flow controlling catheters and methods variously required among amended Claims 1, 18, and 21-22 include many features not disclosed or suggested by the cited Johnson et al. reference, in addition to being simply fundamentally different devices in their general nature. There is no disclosure or suggestion to provide a structure or method that meet the requirements of the claims variously with respect to: separating outer and inner blood flow streams within an abdominal aorta; providing a radially expandable member located along or "on" another expandable tubular member; delivering fluid from outside the body and into an outer blood flow stream around a tubular member and perfusing multiple renal ostia; or decreasing blood flow in an outer blood flow stream around a tubular member and downstream of the renal ostia within an abdominal aorta.

Accordingly, based on the foregoing remarks and amendments to independent Claims 1, 18, and 21-22 subject to this ground for rejection, as well as with respect to the claims that variously depend therefrom, Applicants respectfully reconsideration and withdrawal of this ground for rejection, and that the subject claims be allowed.

Moreover, Applicants note that the amendments to these Claims have been made herein in order to expedite examination of the Application toward a hopeful allowance in the next official action on the merits, and are made without prejudice, admission, waiver, or estoppel with respect to the patentability of the original form of the claims, which Applicants believe are patentably distinct from the cited reference(s) in

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their original form. Applicants reserve the right to pursue the original form of these claims in the future, such as for example through continuation practice.

4. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Certain previously withdrawn claims that variously depend from independent Claim 1 have been herein presented in amended form to allow for their proper re-joinder and allowance in the event their respective base claims are allowed. All amendments herein presented are variously supported by the originally filed Application, and no new matter has been added. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims, allow all pending and re-joined claims, and to pass this Application to allowance for issue.

The Applicant also respectfully requests a telephone interview with the Examiner in the event that there are questions regarding this response, or if the next action on the merits is not an allowance of all pending claims.

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Respectfully submitted,

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